

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

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FENSTER & COMPANY, INTELLECTUAL PROPERTY
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P. O. Box 10256
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Date of mailing (day/month/year)

29 December 2005 (29.12.2005)

Applicant's or agent's file reference

227/04056

IMPORTANT NOTICE

International application No.

PCT/IL2004/000483

International filing date (day/month/year)

08 June 2004 (08.06.2004)

Priority date (day/month/year)

09 June 2003 (09.06.2003)

Applicant

GLUCON INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

4056

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Docketed By <u>IR</u>	
09 JAN 2006	
To: <u>AE</u>	<u>RU</u>
<u>AD</u>	<u>CS</u>
FENSTER & Co.	

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 227/04056	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IL2004/000483	International filing date (day/month/year) 08 June 2004 (08.06.2004)	Priority date (day/month/year) 09 June 2003 (09.06.2003)]	
International Patent Classification (IPC) or national classification and IPC A61B 5/00			
Applicant GLUCON INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 Form PCT/IB/373 (January 2004)	Date of issuance of this report 13 December 2005 (13.12.2005)
	Authorized officer Simin Baharlou Telephone No. +41 22 338 71 30

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 23 DEC 2004

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To:

see form PCT/ISA/220

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43b/s.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.
PCT/IL2004/000483

International filing date (day/month/year)
08.06.2004

Priority date (day/month/year)
09.06.2003

International Patent Classification (IPC) or both national classification and IPC
A61B5/00

Applicant
GLUCON INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000483

Box No. 1 Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000483

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000483

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 19-48

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 19-48
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000483

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-18

Box No. V Reasoned statement under Rule 43b/is.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-18
	No: Claims	
Inventive step (IS)	Yes: Claims	1-18
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-18
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III.

No opinion is given about claims 19-48 because no search report was issued on these claims.

Re Item IV.

The separate inventions/groups of inventions are:

1. 1-18
Apparatus for blood photoacoustic analysis determining the alignment of the device with the blood vessel.
2. 19-48
Apparatus for blood photoacoustic analysis determining the excessive pressure of the device upon the blood vessel.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The common technical features in claim 1 on one side and claim 19 on the other are listed below. This special technical features are not new, because they are disclosed by the prior art document US 6 403,944 (see citations in parentheses).

Apparatus for assaying an analyte of blood in a patient's blood vessel comprising (abstract, claim 1):

- a mounting module adapted so that it can be adhered to the skin of the patient overlying a tissue region comprising a blood vessel (figures 6, 8a, 8b; column 8, lines 41-58, claim 1);
- a sensor unit mounted to the module that generates signals responsive to characteristics of the tissue region (abstract and column 8, lines 42-45; claim 1); and
- a controller that receives the signals and uses received signals to assay the analyte (claim 1)

Furthermore, both subject-matters solve different problems, namely, determining the alignment and the pressure with respect to the blood vessel respectively.

Therefore, the two groups of inventions cannot be considered to have a common single

inventive concept.

As a consequence, claims 1 and 19 are non unitary according to the Rule 13.1 and 13.2 PCT.

Re Item V.

- 1 The following documents are referred to in this communication:
D1 : US 6 403 944 B1 (MACKENZIE HUGH ALEXANDER ET AL) 11 June 2002 (2002-06-11)
D2 : EP 1 205 753 A (ABBOTT LAB) 15 May 2002 (2002-05-15)
D3 : EP 0 919 180 A (TRW INC) 2 June 1999 (1999-06-02)
D4 : WO 02/15776 A (BEN AMI UDI ; NAGAR RON (IL); PESACH BENNY (IL); GLUCON INC (US)) 28 February 2002 (2002-02-28)
- 2 Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parenthesis applying to this document):

Apparatus for assaying an analyte of blood in a patient's blood vessel comprising (abstract, claim 1):

- a mounting module adapted so that it can be adhered to the skin of the patient overlying a tissue region comprising a blood vessel (figures 6, 8a, 8b; column 8, lines 41-58, claim 1);
- a sensor unit mounted to the module that generates signals responsive to characteristics of the tissue region (abstract and column 8, lines 42-45; claim 1);
and
- a controller that receives the signals and uses received signals to assay the analyte (claim 1)

From this, the subject-matter of independent claim 1 differs in that:

the controller determines a degree to which the sensor unit is aligned with the blood vessel.

- 2.1 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT)
The problem to be solved by the present invention may be regarded as:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/IL2004/000483

To monitor the accuracy of the analysis results of the device with regard to the alignment.

- 2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

None of the prior art documents discloses nor suggests a controller determining the alignment of the sensor with the blood vessel, disclosing the influence of this alignment.

- 2.3 Claims 2-18 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.